

**REMARKS****Claim objections**

Claim 9 has been objected to for an informality. The Examiner states that there is a misplaced hyphen between “substitute and “and” in line 3. As amended herein, claim 9 has the offending hyphen deleted. Withdrawal of the objection is therefore respectfully requested.

**35 U.S.C. § 112, second paragraph**

Claims 16-23 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention (Office Action, page 3). Specifically, the Examiner states that the preamble in claims 15 and 16 lacks correspondence to the claim steps in these claims. Claims 17-23 are rejected as being directly or indirectly dependent from claim 15 or 16.

As amended herein, the claim steps in the body of claims 15 and 16 now correspond to the preambles of these claims. In view of these amendments, applicant respectfully requests withdrawal of this rejection and reconsideration of the rejected claims.

**35 U.S.C. § 103(a)**

Claims 1-3, 5-15, 17-22, and 24 have been rejected as being unpatentable over U.S. Pat. No. 5,631,165 (“Chupp”) in view of U.S. Pat. No. 5,200,323 (“Chang”) and Patent Application WO 98/39634 (“Samsoondar”). The applicant respectfully traverses this rejection.

The Examiner states that “Chupp et. al. teach correcting MCH and MCHC in blood by performing the mathematical computations described in b(1)-(2) of claim 9 where the constants to correct dimension units for formula 1 is 10 and for formula 2 is 100 (col. 53, lines 66-67 and col. 54, lines 1-26).” The formulas in Chupp cited by the Examiner use the term HGB

(hemoglobin) while the formulas in independent claims 1, 9, 15 and 16 of the present invention use the term “cellular” hemoglobin. This reflects the fact that hemoglobin measurements are made on an individual cell by cell basis in the present invention as compared to the total hemoglobin measurements made by Chupp. Paragraphs 44 and 45 of the present application contain a detailed description of the dual channel analyzers suitable for the present invention, in particular the second red blood cell channel which “measures the red blood cell concentration and mean cell volume (MCV) and mean cellular hemoglobin concentration (MCHC) of approximately 10,000 individual erythrocytes as they pass through two light scattering detectors.” As stated by the Examiner, “Chupp et. al. do not teach the presence of an extracellular hemoglobin product or oxygen-carrying blood substitute such as recombinant human hemoglobin or the formulas being determined by cell-by-cell measurements.”

The Examiner further states that “Chang et. al. describe adding modified hemoglobin blood substitutes to a human plasma sample with a centrifugation step (abstract) which represents isolation and purification of animal blood, as stated in claims 8, 11 and 18.” The applicant respectfully maintains this represents a misreading of what is in claims 8, 11 and 18. In order for recombinant human hemoglobin to be used as a blood substitute it must be produced in sufficient quantity. One method of producing large quantities of recombinant hemoglobin is to insert the gene for recombinant human hemoglobin into a non-human animal and then purify the expressed recombinant human hemoglobin from the blood of that animal. The claim limitation “wherein the recombinant human hemoglobin is isolated and purified from animal blood.” found in claims 8, 11 and 18 is referring to the this method of producing recombinant hemoglobin and is merely a limitation as to the source of the recombinant hemoglobin. The centrifugation step cited in the abstract of Chang et al. is a recitation of the procedure, well

known in the art, of separating plasma from whole blood and the centrifugation step is performed before the addition of the modified hemoglobin and so has no role in purification of the hemoglobin.

The Examiner further states that “Samsoondar describes screening samples by taking successive sample measurements for interferents and blood substitutes (page 11, second paragraph) which is reasonably interpreted as cell-by-cell measurements, as stated in instant claim 1.” The applicant respectfully submits that this is a misreading of Samsoondar. On page 7 lines 3-4 of Samsoondar, it states that the sample can be “a serum or plasma specimen”. Serum and plasma, by definition, do not contain cells. Therefore the successive measurements referred to on page 11, second paragraph cannot be interpreted to mean cell-by-cell measurements as there are no cells to be measured.

In summary, applicant respectfully asserts that Chupp, Chang and Samsoondar, either alone or in combination, do not teach or suggest the “cell-by-cell measurements” as required by independent claim 1 or the “cellular hemoglobin” as required by independent claim 9, or the “plasma hemoglobin value automatically generated by the automated hematology analyzer” as required by independent claim 15. Applicant respectfully requests withdrawal of this rejection and reconsideration of the rejected independent claims 1, 9, and 15. Applicant also respectfully requests withdrawal of this rejection from claims 2, 3, 5-8, 10-14, 17-22, and 24 which depend from one or more of claims 1, 9, 15 and 16.

**CONCLUSION**

Based on the foregoing amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the objections and rejections of claims and allowance of this application.

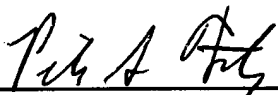
**AUTHORIZATION**

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 0708-4057. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

Respectfully submitted,  
MORGAN & FINNEGAN, L.L.P.

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